

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
00166.0051.JIS04APPLICATION NO. 09/252,486  
(Cont. of 09/005,549)APPLICANTS  
Mesens et al.FILING DATE  
HerewithGROUP 1613  
To be assigned.

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2						
	AB2						
JKM	AC2	3,197,180	07/1965	Bates et al.	514	258	
	AD2	3,523,906	08/1970	Vrancken et al.	424	490	
	AE2	3,691,090	09/1972	Kitajima et al.	424	426	
	AF2	3,737,337	06/1973	Schnoring et al.	544	282	
	AG2	3,891,570	06/1975	Fukushima et al.	524	258	
	AH2	3,923,288	12/1975	King et al.	427	213	
	AI2	3,960,757	06/1976	Morishita et al.	424	497	
	AJ2	4,034,965	07/1977	King et al.	424	1,25	
JKM	AK2	4,111,402	09/1978	Barbini et al.	424	1,33	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1						Yes No
	AM1						Yes No
	AN1						Yes No
	AO1						Yes No
	AP1	EP 0 052 510	05/1982	Europe			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKM	AR	4	Baker, J.R., "Motionless Mixers Stir Up New Uses", Chemical Engineering Progress:32-38 (June 1991)
JKM	AS	4	Borison, R.L. et al., "Clinical Overview of Risperidone", in: Meltzer, H., Y., ed., Novel Antipsychotic Drugs, Raven Press, Ltd., N.Y.: 233-239 (1992)
JKM	AT	4	Chemineer, "Kenics Static Mixers", Bulletin 800:1-11 (1986)

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11/12/99

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FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
00166.0051.US04APPLICATION NO. 09/252,400  
(Cont. of 08/085,544)APPLICANTS  
Messers et al.FILING DATE  
HerewithGROUP 1413  
To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
Jkm	AA3	4,128,641	12/1978	Itil et al.	424	489	
	AB3	4,201,482	05/1980	Imhäuser et al.	424	501	
	AC3	4,208,136	06/1980	King et al.	424	501	
	AD3	4,329,331	05/1982	Kallick et al.	424	497	
	AE3	4,335,127	06/1982	Vandenberg et al.	424	489	
	AF3	4,337,261	06/1982	Shutske et al.	424	489	
	AG3	4,352,811	10/1982	Strupczewski	424	497	
	AH3	4,443,451	04/1984	Kennis et al.	424	497	
	AI3	4,485,107	11/1984	Kennis et al.	424	497	
	AJ3	4,489,055	12/1984	Couvreux et al.	424	497	
Jkm	AK3	4,511,258	04/1985	Federighi et al.	424	501	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
Jkm	AL2	EP 0 071 454	02/1983	Europe	—	—	Yes No
Jkm	AM2	EP 0 129 619	01/1985	Europe	—	—	Yes No
Jkm	AN2	EP 0 195 450	09/1986	Europe	—	—	Yes No
Jkm	AO2	EP 0 248 531	12/1987	Europe	—	—	Yes No
Jkm	AP2	EP 0 266 119	05/1988	Europe	—	—	Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

Jkm	AR	2	Glazer, W.M. et al., "Depot Neuroleptic Therapy: An Underutilized Treatment Option", J. Clin. Psychiatry 53 (12):426-433 (December, 1992)
Jkm	AS	2	Heinrich, K. et al., "Experimental Comparison of the Efficacy and Compatibility of Risperidone and Clozapine in Acute Schizophrenia", in: Kane, J.M. (ed), Risperidone: Major Progress in Antipsychotic Treatment. Oxford Clinical Communications, Oxford:37-39 (1991)
Jkm	AT	2	Photocopy of an unofficial English Translation of Japanese Patent Application No. Hei-04 (1992)-332441, "Sustained-Release Microsphere and Process for Producing the Same," filed by Yoshitomi Pharmaceutical Industries, Ltd., which is the priority document of PCT Application No. 94/10982, pp. 1-12

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## INFORMATION DISCLOSURE STATEMENT

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00166.0051.US04APPLICATION NO. 09/252,466  
(Cont. of 09/005,549)APPLICANTS  
Mesens et al.FILING DATE  
HerewithGROUP 1013  
To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
JKM	AA4	4,529,727	07/1985	Kennis et al.	424	489	
	AB4	4,530,840	07/1985	Tice et al.	424	497	
	AC4	4,542,025	09/1985	Tice et al.	424	497	
	AD4	4,585,482	04/1986	Tice et al.	424	497	
	AE4	4,616,440	09/1986	King et al.	424	501	
	AF4	4,616,937	10/1986	King et al.	424	501	
	AG4	4,643,584	02/1987	Allocca et al.	424	501	
	AH4	4,665,075	03/1987	Vandenberk et al.	424	489	
	AI4	4,675,189	06/1987	Kent et al.	424	489	
	AJ4	4,677,191	06/1987	Tankana et al.	424	486	
JKM	AK4	4,683,288	07/1987	Tankana et al.	424	486	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
JKM	AL3	WO 88/01165	02/1988	PCT			Yes No
JKM	AM3	WO 91/13595	09/1991	PCT			Yes No
JKM	AN3	WO 91/17772	11/1991	PCT			Yes No
JKM	AO3	1 212 730	11/1970	United Kingdom			Yes No
JKM	AP3	1 351 811	03/1974	United Kingdom			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKM	AR	6	Janssen and Niemegeers, "Chemistry and pharmacology of compounds related to 4-(4-hydroxy-4-phenyl-piperidino)-butyrophenone", <i>Arzneim.-Forsch. (Drug Res.)</i> 12:765-767 (1959)
JKM	AS	6	Janssen, P.A.J. et al., "Is it Possible to Predict the Clinical Effects of Neuroleptic Drugs (Major Tranquilizers) from Animal Data?", <i>Arzneim.-Forsch. (Drug Res.)</i> 10:1196-1206 (1965)
JKM	AT	6	Koch Engineering Company Inc., "Static Mixing Technology", Articles:1-15 (1991)

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00166.0051.US04APPLICATION NO. 09/252,486  
(Cont. of 09/005,549)APPLICANTS  
Messers et al.FILING DATE  
HerewithGROUP 1613  
To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
JKM	AAS	4,689,330	08/1987	Janssen et al.	424	497	
	ABS	4,696,258	09/1987	Magrath et al.	424	497	
	ACS	4,731,205	03/1988	McMulty et al.	424	497	
	ADS	4,737,500	04/1988	Sorg et al.	424	486	
	AES	4,753,535	06/1988	King et al.	424	489	
	AFS	4,765,204	08/1988	Buchholz et al.	424	501	
	AGS	4,793,713	12/1988	King et al.	424	489	
	AHS	4,798,786	01/1989	Tice et al.	424	489	
	AIS	4,808,007	02/1989	King et al.	424	501	
	AJS	4,835,139	05/1989	Tice et al.	424	486	
JKM	AKS	4,897,268	01/1990	Tice et al.	424	501	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
JKM	AL4	2 015 360	09/1979	United Kingdom			Yes No
JKM	AM4	2 120 113	11/1983	United Kingdom			Yes No
JKM	AM4	0 196 132	10/1986	Europe			Yes No
JKM	AO4	2 246 573	02/1992	United Kingdom			Yes No
JKM	AP4	0 486 959	05/1992	Europe			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	Z	<del>Koch Engineering Company Inc., "All Mixing Problems Are Not Alike", 1 page, Product Brochure</del>
	AS	Z	<del>Keflo Corporation, "Static In-Line Mixers", 4 pages, Product Brochure</del>
	AT	Z	<del>Komax Systems Inc., "Triple Action Static Mixers", 2 pages, Product Brochure</del>

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## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
00166-0051-JS04APPLICATION NO. 09/252,466  
(Cont. of 09/005,529)APPLICANTS  
Mesens et al.FILING DATE  
HerewithGROUP 1013  
To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
JKM	AA6	4,936,689	06/1990	Federighi et al.	424	489	
JKM	AB6	5,075,109	12/1991	Tice et al.	424	501	
JKM	AC6	5,102,872	04/1992	Singh et al.	424	499	
	AD6						
	AE6						
	AF6						
	AG6						
	AH6						
	AI6						
	AJ6						
	AK6						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
JKM	AL5	WO 94/10982	07/1994	WIPO			Yes No
	AM5						Yes No
	AN5						Yes No
	AO5						Yes No
	AP5						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKM	AR	8	Leysen, J.E. et al., "In vitro receptor binding and neurotransmitter uptake inhibition profile of R 64 766, R 76 477, R 78 543 and R 78 544", Janssen Research Foundation, Beerse, Belgium, N 79120, Preclinical Research Report R 64 766/28, 11 pages (January 1991)
JKM	AS	8	Mertens, C., "Long-term treatment of chronic schizophrenic patients with risperidone", in: Kane, J.M. (ed), Risperidone: Major Progress in Antipsychotic Treatment, Oxford Clinical Communications, Oxford:44-48 (1991)
JKM	AT	8	Mutsakis et al., "Advances In Static Mixing Technology", Chemical Engineering Progress:42-48 (July 1986)

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## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
00166.0051:US04APPLICATION NO. 09/252,966  
(Cont. of 09/005,549)APPLICANTS  
Mesens et al.FILING DATE  
HerewithGROUP 1613  
To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKM	AR	2	Niemegeers and Janssen, "A Systematic Study of the Pharmacological Activities of Dopamine Antagonists", in: <i>Life Science</i> 24(24):2201-2216, Pergamon Press Ltd (1979)
JKM	AS	2	Niemegeers et al., "Antiemetic Specificity of Dopamine Antagonists", <i>Psychopharmacology</i> 78:210-213 (1982)
JKM	AT	2	Streiff, F., "In-line Dispersion and Mass Transfer using Static Mixing Equipment", <i>Sulzer Technical Review</i> 3:108-114 (1977)

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FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

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00166.0051.US04APPLICATION NO. 09/252,486  
(GORE OF 09/005,549)APPLICANTS  
Mesens et al.FILING DATE  
HerewithGROUP 1413  
To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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	AH						
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	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	10	Abstract of WO 94/10982, Kino et al., "Sustained-release Microspheres Requiring No Surgical Implant Contains Hydrophobic Antipsychotic Encapsulated in Biodegradable Polymer, Allowing Prolonged Therapeutic Effect by Infrequent Administration"
	AS	10	
	AT	10	

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ATTY. DOCKET NO. 00166.0051.US04

APPLICATION NO.

To be assigned 09/252,466  
(Cont. of 09/005,549)FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENTAPPLICANT  
Mesens *et al.*

FILING DATE Herewith

GROUP 1613  
To be assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
<b>JKM</b>	AA1	5,792,477	08/1998	Rickey <i>et al.</i>	<b>424</b>	<b>501</b>	
<b>JKM</b>	AB1	5,650,173	07/1997	Ramstack <i>et al.</i>	<b>424</b>	<b>489</b>	
	AC1						
	AD1						
	AE1						
	AF1						
	AG1						
	AH1						
	AI1						
	AJ1						
	AK1						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATIO N
	AL1						Yes No
	AM1						Yes No
	AN1						Yes No
	AO1						Yes No
	AP1						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	
	AS	1	
	AT	1	

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DATE CONSIDERED

**11/12/99**



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## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.

00166.0051. US04

APPLICATION NO.

In be assigned 0 9/252,466

(Cons. of 09/005,549)

APPLICANTS

Mesens et al.

FILING DATE

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GROUP 1413

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
Jkm	AA1	3,773,919	11/1973	Boswell et al.	424	497	
	AB1	4,342,870	08/1982	Kennis et al.	424	497	
	AC1	4,389,330	06/1983	Tice et al.	424	489	
	AD1	4,458,076	07/1984	Strupczewski	424	501	
	AE1	4,804,663	02/1989	Kennis et al.	424	486	
	AF1	4,883,666	11/1989	Sabel et al.	424	497	
	AG1	4,940,588	07/1990	Sparks et al.	424	497	
	AH1	4,994,281	02/1991	Muranishi et al.	424	489	
	AI1	5,008,114	04/1991	Lovrecich	424	497	
	AJ1	5,158,952	10/1992	Janssen et al.	424	501	
Jkm	AK1	5,407,609	04/1995	Tice et al.	424	497	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
Jkm	AL1	0 368 388	05/1990	Europe			Yes No
Jkm	AM1	WO 90/13361	11/1990	WIPO			Yes No
Jkm	AN1	WO 94/25460	11/1994	WIPO			Yes No
Jkm	AO1	WO 95/13799	05/1995	WIPO			Yes No
	AP1						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

Jkm	AR	1	Megens, A.A.H.P. et al., "Comparative Pharmacology of Risperidone, Its Major Metabolite R 76 477 <sup>(*)</sup> and the Corresponding Enantiomers R 78 543 <sup>(*)</sup> and R 78 544 <sup>(*)</sup> in Rats and Dogs", Janssen Research Foundation, Beerse Belgium, N74694, Preclinical Research Report R 64 766/23 (June 1990).
Jkm	AS	1	Megens, A.A.H.P., et al., "In Vivo Pharmacological Profile of 9-Hydroxyrisperidone, the Major Metabolite of the Novel Antipsychotic Risperidone: Comparison With Risperidone and Haloperidol", Janssen Research Foundation, Beerse, Belgium, N 96295, Preclinical Research Report R 64 766/R 76 477 (May 1993).
Jkm	AT	1	Suzuki, K., et al., "Microencapsulation and Dissolution Properties of a Neuroleptic in a Biodegradable Polymer, Poly(d,l-lactide)", Journal of Pharmaceutical Sciences, Vol. 74, No. 1, 21-26 (January 1985).

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APPLICATION NO.

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(Cont. of 09/005,549)

09/252,464

APPLICANTS

Mesens et al.

FILING DATE

Herewith

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To be assigned

1613

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
JKM	AA2	5,453,425	09/1995	Francois et al.	424	497	
JKM	AB2	5,478,564	12/1995	Vantier et al.	424	497	
	AC2						
	AD2						
	AE2						
	AF2						
	AG2						
	AH2						
	AI2						
	AJ2						
	AK2						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2						Yes No
	AM2						Yes No
	AN2						Yes No
	AO2						Yes No
	AP2						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKM	AR	2	Ramtoola, Z., et al., "Release Kinetics of Fluphenazine from Biodegradable Microspheres", <i>Journal of Microencapsulation</i> , Vol. 8, No. 4, 415-423 (1992).
JKM	AS	2	Chang, R., et al., "Dissolution Characteristics of Polycaprolactone-Polylactide Microspheres of Chlorpromazine", <i>Drug Development and Industrial Pharmacy</i> , Vol. 12, No. 14, 2355-2380 (1986).
JKM	AT	2	Maulding, H.V., et al., "Biodegradable Microcapsules: Acceleration of Polymeric Excipient Hydrolytic Rate By Incorporation of a Basic Medicament", <i>Journal of Controlled Release</i> , 3: 103-117 (1986).

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Joseph K. M. Kane

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09/252,466

APPLICANTS

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	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
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	AG3						
	AH3						
	AI3						
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

JKM	AR	3	Leysen, J.E., et al., "Biochemical Profile of Risperidone, a New Antipsychotic", The Journal of Pharmacology and Experimental Therapeutics, Vol. 247, No. 2, 661-670 (1988).
JKM	AS	3	Janssen, P.A.J., et al., "Pharmacology of Risperidone (R 64 766), a New Antipsychotic With Serotonin - S <sub>2</sub> and Dopamine - D <sub>2</sub> Antagonistic Properties", The Journal of Pharmacology and Experimental Therapeutics, Vol. 244, No. 2, 685-693 (1988).
JKM	AT	3	Chouinard, G., et al., "A Canadian Multicenter Placebo-Controlled Study of Fixed Doses of Risperidone and Haloperidol in the Treatment of Chronic Schizophrenic Patients", Journal of Clinical Psychopharmacology, Vol. 13, No. 1, 25-40 (1993).

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